

ARMOUR et al.
Appl. No. 09/674,857
April 3, 2007

RECEIVED
CENTRAL FAX CENTER

APR 03 2007

REMARKS/ARGUMENTS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

The Examiner's comments regarding the relationship between claims 55 and 56 and claims 66 and 67 is noted. The above-noted cancellation of claims 66 and 67 moots the Examiner's concern.

The claims have been revised in a manner that is believed to address the Examiner's objections and the rejection under 35 USC 112, second paragraph (see detailed comments that follow). Claims 22, 66 and 67 have been cancelled without prejudice. New claims 71-78 have been added. The new claims do not add new matter or raise new issues as they correspond generally to the subject matter of dependent claims 33, 42 and 46.

Claims 21, 22, 25, 28, 29, 32, 41, 55, 56, 59, 62, 63, 66 and 67 stand rejected under 35 USC 112, second paragraph. Withdrawal of the rejection is believed to be in order for the reasons that follow.

The Examiner's concerns are considered in turn below:

(i) Claim 21 - "...2, 3 or 4 amino acids...":

Molecules according to the present invention can be created making only 2 changes in at least 1 block. This can be illustrated by considering Appendix I which shows a line up of the native C_H2 sequences of IgG1, G2 and G4, and also various modified molecules of the present invention.

The '*'s after G1, G2 and G4 simply show the differences between them for ease of reference.

ARMOUR et al.
Appl. No. 09/674,857
April 3, 2007

The "*"s after the various modified molecules of the invention show the mutations with respect to their parent. All of these were prepared by Applicants and tested in the specification, except G2(hyp) which is included for illustrative purposes.

Certain of the modified molecules of the claimed invention have the required blocks of amino acids i.e.:

233P, 234V, 235A, 236G and 327G, 330S and 331S

However, these 7 identities can be achieved by making, for example, 2 changes in at least 1 region (note G2hyp, which needs only 2 changes since IgG2 already has G327).

Likewise, and with reference to G1Δac and G4Δc, note the 3 changes to introduce amino acids from a second human IgG chain.

In view of the above and attached Appendix, Applicants submit that it should not be necessary nor would it be appropriate to delete "2". However, "4" has been deleted.

(ii) "...and is at least 98% identical to a C_H2 sequence (residues 231-340) from human IgG1, IgG2 or IgG4 having said modified amino acids"

The Examiner's attention is directed to the fact that the reference point for % identity is a native sequence including the modifications. Thus this is, in effect, claiming sequences that are >98% identical to exemplified sequences of the present invention (i.e., native sequences having the modifications, e.g., G1Δac, G2(hyp), G4Δc etc.). Since the claims only cover sequences that have the required blocks of amino acids, i.e.:

233P, 234V, 235A, 236G and 327G, 330S and 331S,

ARMOUR et al.
Appl. No. 09/674,857
April 3, 2007

the 98% identity language, in effect, allows a further 2 changes within the (defined, modified) 110 amino acid CH₂ sequence. This represents a reasonable balance between Applicants' contributions and the scope of protection sought.

(iii) Claim 22 – “wherein 2 amino acids in 1 region of the CH₂ domain...”

Claim 22 has been cancelled without prejudice.

(iv) “Prevent” and “otherwise”

Claims 25 and 59 have been revised to delete these terms.

(v) Claim 28 – “wherein said contacting is effected in a patient”

Claim 28 has been amended in a manner suggested by the Examiner.

(vi) Claim 29 – “administered to a patient”

Claim 29 has been revised as suggested by the Examiner.

(vii) Claim 32 – “, and is at least 98% identical ...”

Please see explanation at (ii) above which applies analogously here.

(viii) Claim 41 – “... is at least 98% identical ...”

Please see explanation at (ii) above which applies analogously here. Thus this is, in effect, claiming sequences that are >98% identical to exemplified sequences of the present

ARMOUR et al.
Appl. No. 09/674,857
April 3, 2007

invention (i.e., native sequences having the modifications, e.g., G1Δab, G2Δa, G4Δb, etc.).

Since the claims only cover sequences that have the required blocks of amino acids, i.e.:

233P, 234V, 235A, 236- and 327G, 330S and 331S,

the 98% identity language, in effect, allows a further 2 changes within the (defined, modified) 110 amino acid C_{H2} sequence.

(ix) Claim 55 – "... 2, 3 or 4 amino acids ..."

The Examiner's attention is directed to the explanation at (i) above which applies analogously here. However, in this claim, all the encompassed modified molecules of the claimed invention have the required blocks of amino acids i.e.:

233P, 234V, 235A, 236 - and 327G, 330S and 331S

However these 7 identities can be achieved by making e.g. 2 changes in at least 1 region (note G2Δa), or 3 changes (note G4Δb) or 4 changes (note G4Δb, G1Δab,) to introduce amino acids from a second human IgG chain. Therefore, Applicants submit it should not be necessary nor would it be appropriate to delete "2".

(x) Claim 55 – "... wherein said chimeric ..."

The Examiner's attention is directed to the explanation at (viii) above which applies analogously here.

(xi) Claim 56 – "wherein 2 amino acids ..."

Attention is directed to the explanation at (ix) above which applies analogously here.

ARMOUR et al.
Appl. No. 09/674,857
April 3, 2007

(xii) Claim 62 – “wherein said contacting is effected ...”

Claim 62 please has been revised as suggested by the Examiner.

(xiii) Claim 63 – “wherein the binding molecule ...”

Claim 63 has been revised as suggested by the Examiner.

In view of the above, reconsideration and withdrawal of the rejection are requested.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By:

Mary J. Wilson

Mary J. Wilson
Reg. No. 32,955

MJW:tat
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100